Remarks/Arguments:

This Request for Continued Examination with amendments and remarks is responsive to the Office Action of December 18, 2006. A Notice of Appeal in this matter was filed on June 13, 2007.

Claims 55 and 58 are amended to specify that the immunogenic fragment must be at least 15 amino acids long and composed of a contiguous sequence of amino acids within the sequence of amino acids 1-47 or 104-276 of SEQ ID NO:2. Support for this amendment is found in original claim 28, filed by preliminary amendment with the national application, and in the listing of SEQ ID NO:2.

Claims 59-62 and 64-66 are amended to better correspond to the claims from which they depend.

Claims 56 and 57 are amended to correct typing errors that omitted the term "acid."

No new matter is added by these amendments.

I. Rejections under 35 USC § 112 - Written Description

Claims 55, 58-64 and 66-68 stand rejected under Section 112 as insufficiently described. The Office Action maintains that no parts of the polypeptide structure necessary for function has been identified (OA page 3); that no functional fragments have been described (OA page 4); and that a representative number of fragments have not been described by structural features common to the claimed fragments or structural features related to function (OA page 6). Applicant respectfully traverses this rejection for the reasons discussed below.

As pointed out by the Office Action on pages 4-5, *U.C. v. Lilly,* 119 F.3d 1559 (Fed. Cir. 1997) requires "a precise definition, such as by structure, formula, [or] chemical name," and *Enzo v. Genprobe*, 296 F.3d 1316 (Fed. Cir. 2002) states that "the written description requirement can be met by showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... *i.e.*, complete of partial structure, other physical and/or chemical properties, functional characteristics coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." In addition, "[f]or some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length," (emphasis added),

MPEP Section 2163(2)(A)(3). "Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP Section 2163(2)(A)(3)(i).

The specification provides structure and formula by giving the amino acid sequence of SEQ ID NO: 2 (complete or partial structure) and restricting the possible sequences of the fragments to those found within amino acids 1-47 and 104-276 of SEQ ID NO:2. As the Office Action quotes from *Lilly* on page 5, "[A] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus..." (emphasis added). Thus for DNA and polypeptide sequences, a recitation of the sequence alone is sufficient to describe the claimed nucleotide or polypeptide sequences claimed. Thus, the *Lilly* requirements are satisfied by Applicant's listing of SEQ ID NO:2, which recites every possible fragment of 15 contiguous amino acids between amino acids 1-47 and 104-276 of SEQ ID NO:2. Identification of structural features common to the members of the genus are not an additional requirement to a sequence listing, but, rather, an alternative means of description.

In addition, the specification describes fragments on page 5, lines 13-20, including information on structural domains that may be excluded from the fragment. Page 6, lines 1-17, of the specification describe in detail preferred fragments and the structural features of the full-length polypeptide that are important for function and would be useful to include in a fragment. Recombinant fusion proteins comprising the claimed fragments are described in detail on page 7, line 5 to page 8 line 9, including a description of fusion partner proteins that can be used to enhance the immunogenicity of the selected fragments. Immunogenic compositions and vaccines are described on page 30, line 20 to page 32, line 28, specifically as comprising "a recombinant BASB111 polynucleotide and/or polypeptide encoded therefrom ... or other polypeptide of the invention." Such polypeptides are properly and adequately described by SEQ ID NO:2. Accordingly, the *Enzo* requirements of complete or partial strucure, other physical and chemical properties, and correlation between function and structure are satisfied, and the claimed polypeptides, polypeptide fragments, immunogenic compositions, and vaccines are sufficiently described.

The above cited paragraphs of the specification in combination with SEQ ID NO:2 sufficiently distinguish the claimed invention from other materials and would lead one of skill in

the art to the conclusion that the applicant was in possession of the claimed species. Accordingly, Applicant requests that the written description rejections against claims 55, 48-64 and 66-68 be withdrawn.

II. Rejections under 35 USC § 112 - Enablement

Claims 55 and 58-68 stand rejected under Section 112 for lack of enablement. The Office Action asserts that no immunogenic fragments have been specifically shown, by working example, to produce antibodies that bind to SEQ ID NO:2, and that the three-dimensional structure of the antigen, which is important in determining whether the antigen is immunogenic and what antibodies will bind to the target polypeptide, has not been addressed. The Office Action maintains that it would require undue experimentation to determine which fragments of SEQ ID NO:2 would produce antibodies that bind to a polypeptide having the sequence of SEQ ID NO:2, and, therefore, these claims are not enabled.

Applicant respectfully disagrees. In *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed Cir. 2004), it was held that disclosure of an antigen, characterized by structure, formula, chemical name, or physical properties allowed an applicant to claim an antibody by its binding affinity to that antigen. Applicant has described a polypeptide antigen having the amino acid sequence of SEQ ID NO:2. Having adequately described this antigen by sequence, Applicant may properly claim the genus of antibodies that bind to this antigen. This genus of antibodies comprises those that bind to any portion of SEQ ID NO:2, and may accordingly include any antibodies raised from fragments of SEQ ID NO:2. As the Office Action points out on page 12, Roitt *et al*, teach that it is possible to produce antibodies to almost any part of an antigen. Therefore, any claimed fragment of SEQ ID NO:2 will be immunogenic and can be used to raise antibodies.

In addition, the specification presents working examples demonstrating that the polypeptide of SEQ ID NO:2 is immunogenic and can generate antibodies that bind to this peptide (Examples 5-7). It is known in the art, and pointed out on pages 12-13 of the Office Action, that such antibodies would have been produced in response to specific regions of the SEQ ID NO:2 sequence, that is, to epitopes, or fragments, of the polypeptide. Applicant is not required to demonstrate by working example that every possible fragment is cabable of making an antibody that binds to the polypeptide of SEQ ID NO:2. It is sufficient to demonstrate that the polypeptide of SEQ ID NO:2 is immunogenic and has at least one immunogenic region.

Those of ordinary skill in the art would understand, particularly in light of the guidance provided by the specification, that the same methodology described in Examples 5-7 could be used to make and use isolated immunogenic fragments, whose ability to bind a polypeptide of SEQ ID NO:2 can be determined by routine experimentation.

Furthermore, the number of possible fragments having at least 15 contiguous amino acids within amino acids 1-47 and 104-276 of SEQ ID NO:2 is finite, and methods of testing for the immunogenicity of peptides are also merely routine. For example, methods for screening serum for the presence of antibodies are commonly known in the art and commercial kits may be purchased for this purpose.

As stated in *In re Wands*, "[t]he nature of monoclonal antibody technology is that it involves screening..." and "methods for obtaining and screening monoclonal antibodies were well known in 1980." 853 F.2d 731, 740, 737 (Fed. Cir. 1988). Furthermore, "a considerable amount of experimentation is permissible, if it is merely routine...". *Id.* at 737. Following the "Wands" factors, the court then determined, in *In re Wands*, that screening was necessary to produce an antibody to a particular antigen and was routine in the art of monoclonal antibody production. *Id.* at 740. Screening is routine in the production of all antibodies, not just monoclonal antibodies, because it is important to identify antibodies with the greatest binding affinity. Similarly, screening is routine in the art of vaccine production to identify antigens and antibodies with the greatest vaccine potential. Example 8 describes in detail how to screen antibodies for vaccine potential.

Accordingly, Applicant submits that routine screening employed in the general course of antibody and vaccine production may readily be used to determine whether a particular peptide fragment will raise antibodies, *i.e.*, is immunogenic, whether these antibodies are capable of binding to a polypeptide having the sequence of SEQ ID NO:2, and whether these antibodies have vaccine potential. The methods for producing and screening antibodies and vaccines are well-established and well known to those of ordinary skill in the art. The specification also lists articles and laboratory manuals that describe these methods and gives examples using these methods. Therefore, the experimentation required to identify immunogenic fragments that can bind to a polypeptide of SEQ ID NO:2 and be used as vaccines is merely routine, and not undue.

Therefore, Applicant respectfully requests that the Section 112 rejections for nonenablement against claims 55 and 58-68 be withdrawn.

III. Rejections under 35 USC § 102(e)

Claims 55, 58, 59, 61-64,and 66-68 stand rejected under Section 102(e) as anticipated by Breton, U.S. Pat. No. 6,673,910.

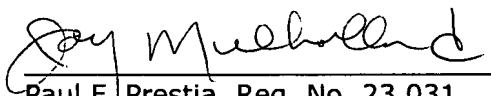
Claims 55 and 58 have been amended to describe specific amino acid sequences within SEQ ID NO:2 which may comprise the claimed immunogenic polypeptides. Breton does not disclose sequences of 15 or more contiguous amino acids within the regions of SEQ ID NO:2 claimed in amended claims 55 and 58. Claims 59, 61-64, and 66-68 depend from claim 55 or 58. Accordingly, Breton does not anticipate any of these amended claims.

Therefore, Applicant respectfully requests that the Section 102(e) rejection of claims 55, 58, 59, 61-64,and 66-68 be withdrawn.

Conclusion

It is respectfully submitted that the claims are in condition for immediate allowance and a notice to this effect is solicited. The Examiner is invited to phone applicant's attorney if it is believed that a telephonic interview would expedite prosecution of the application.

Respectfully submitted,



Paul F. Prestia, Reg. No. 23,031
Joy Mulholland, Reg. No. 47,810
Attorneys for Applicant

JM/lrb

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P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

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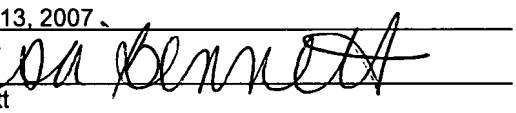

Lisa Bennett

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